

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

HELEN E. HOUTZ,	:	Case No. 4:14-cv-0536
	:	
Plaintiff,	:	
	:	
v.	:	(Judge Brann)
	:	
ENCORE MEDICAL	:	
CORPORATION, ENCORE	:	
MEDICAL, L.P., DJO SURGICAL	:	
and DJO INCORPORATED,	:	
	:	
Defendants.	:	

MEMORANDUM
December 10, 2014

Defendants Encore Medical Corporation, Encore Medical, L.P., DJO Incorporated, and DJO Surgical (hereinafter, “Defendants”) filed a Motion to Dismiss Plaintiff Helen E. Houtz’s Amended Complaint for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Defs.’ Mot. Dismiss, May 7, 2014, ECF No. 11 (hereinafter “Defs.’ Mot.”). Plaintiff’s Amended Complaint, filed April 25, 2014, alleges one count for negligence, based on various theories of liability, and one count for manufacturing defect based upon a theory of strict liability. Pl.’s Compl., Apr. 25, 2014, ECF No. 10 (hereinafter “Pl.’s Compl.”). Defendants seek to dismiss Plaintiff’s Amended Complaint against them in its entirety. This Court retains

diversity jurisdiction pursuant to 28 U.S.C. § 1332. Consequently, Pennsylvania substantive law applies. *See, e.g., Erie R. Co. v. Tompkins*, 304 U.S. 64, 91-92 (1938).

For the reasons discussed, Defendants' Motion to Dismiss is granted in part and denied in part. Insofar as Plaintiff's Amended Complaint asserts a claim for negligent failure to test and negligent sale in Count I, those claims are dismissed with prejudice. Insofar as Plaintiff's Amended Complaint asserts a claim for negligent failure to warn and negligent design in Count I, those claims are dismissed without prejudice with leave to file a second amended complaint in accordance with this Court's decision. Defendants' Motion to Dismiss is denied with regard to Plaintiff's claim in Count II for manufacturing defect based upon a theory of strict liability.

I. BACKGROUND

On February 24, 2014, Plaintiff initiated the above-captioned civil action by filing a Complaint in the Court of Common Pleas of Centre County, Pennsylvania. On March 30, 2014, Defendants removed the case to this Court pursuant to 28 U.S.C. §§ 1332(a), 1441(a), and 1446. On April 25, 2014, Plaintiff filed an Amended Complaint with this Court alleging one count of negligence based upon various theories of liability and one count of strict liability due to a manufacturing defect. On May 7, 2014, Defendants moved to dismiss Plaintiff's Amended

Complaint in its entirety. The following allegations are taken from Plaintiff's Amended Complaint and are accepted as true for the purposes of the instant motion.

This case arises from the implantation and subsequent failure of an artificial knee replacement device produced by the Defendants and implanted into the Plaintiff on or about February 7, 2000 during a bilateral knee replacement surgery. Pl.'s Compl. ¶ 8. The surgery was performed by Kenneth Cherry, M.D., at the Center Valley Community Hospital, State College, Pennsylvania. *Id.* ¶ 6, 8. Prior to the surgery, Plaintiff was provided no indication or warning by Defendants that the artificial knee's post tibial insert and/or polyethylene was destined to fail or had any particular life expectancy. *Id.* ¶ 17. Though the knee replacements initially functioned satisfactorily¹, in April 2011, Plaintiff experienced an audible popping sensation in her left knee as she stood up from a sitting position. *Id.* ¶ 10. This caused her knee to become unstable and painful, leading her to seek medical attention at Mount Nittany Medical Center. *Id.* ¶ 10.

Once again, Dr. Cherry examined the Plaintiff and concluded that Plaintiff had suffered a failed tibial post, which is the portion of the knee implant that attaches to the lower half of an individual's leg. *Id.* ¶ 11-13. As a result, Dr. Cherry ultimately conducted a revision of the left tibial insert, the component of

¹ In her Brief in Opposition to Defendants' Motion to Dismiss, Plaintiff asserts that the implant in her right knee had previously failed and needed to be replaced in October 2001, although, curiously, she asserts no such thing in her Amended Complaint.

the knee that had failed. *Id.* ¶ 14. In his explanation of the failure, Dr. Cherry reported that “[t]he post is missing and marked irregularity of this region is noted. . . . The smaller fragment appears to represent the missing post and is markedly irregular at one end.” *Id.* ¶ 16. As a result of the failure of the tibial post and the subsequent surgery, Plaintiff has suffered pain, discomfort, and instability in her left knee, and past and ongoing medical treatment, which may continue indefinitely. *Id.* ¶ 23(a)-(f).

II. DISCUSSION

A. Motion to Dismiss Standard

When considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a court must view all allegations stated in the complaint as true and construe all inferences in the light most favorable to plaintiff. *Hishon v. King & Spaulding*, 467 U.S. 69, 73 (1984); *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993). However, “the tenet that a court must accept as true all of the [factual] allegations contained in the complaint is inapplicable to legal conclusions.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citations omitted). In ruling on such a motion, the court primarily considers the allegations of the pleading, but is not required to consider legal conclusions alleged in the complaint. *Kost*, 1 F.3d at 183. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Iqbal*, 556 U.S. at 678. At the

motion to dismiss stage, the court considers whether plaintiff is entitled to offer evidence to support the allegations in the complaint. *Maio v. Aetna, Inc.*, 221 F.3d 472, 482 (3d Cir. 2000).

A complaint should only be dismissed if, accepting as true all of the allegations in the amended complaint, plaintiff has not pled enough facts to state a claim to relief that is plausible on its face. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 561 (2007). “Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Iqbal*, 556 U.S. at 663-664.

“In considering a Rule 12(b)(6) motion, we must be mindful that federal courts require notice pleading, as opposed to the heightened standard of fact pleading.” *Hellmann v. Kercher*, No. 07-1373, 2008 WL 1969311 at * 3 (W.D. Pa. May 5, 2008) (Lancaster, J.). Federal Rule of Civil Procedure 8 “requires only a ‘short and plain statement of the claim showing that the pleader is entitled to relief,’ in order to ‘give the defendant fair notice of what the...claim is and the grounds on which it rests,’” *Bell Atlantic Corp. v. Twombly*, 550 U.S. at 554 (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). However, even under this lower notice pleading standard, a plaintiff must do more than recite the elements of a cause of action, and then make a blanket assertion of an entitlement to relief. See *Hellmann*, 2008 WL 1969311 at *3. Instead, a plaintiff must make a factual showing of his entitlement

to relief by alleging sufficient facts that, when taken as true, suggest the required elements of a particular legal theory. *See Twombly*, 550 U.S. at 561. “[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - - but it has not “shown” - - “that the pleader is entitled to relief.” Iqbal, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)).

The failure-to-state-a-claim standard of Rule 12(b)(6) “streamlines litigation by dispensing with needless discovery and factfinding.” *Neitzke v. Williams*, 490 U.S. 319, 326-27 (1989). A court may dismiss a claim under Rule 12(b)(6) where there is a “dispositive issue of law.” *Id.* at 326. If it is beyond a doubt that the non-moving party can prove no set of facts in support of its allegations, then a claim must be dismissed “without regard to whether it is based on an outlandish legal theory or on a close but ultimately unavailing one.” *Id.* at 327.

B. Count I Negligence

In her Amended Complaint, Plaintiff asserts one count for negligence based on various theories of liability. As only two of these theories are even viable theories of negligence under Pennsylvania law, this Court will address each theory in turn.

1. Negligent Failure to Test

One theory on which Plaintiff bases her claim of negligence is on

Defendants' "failure to properly test and/or inspect the Encore knee to determine whether it could be used for its intended purpose without injury to those persons who were implanted with such device." Pl.'s Compl. ¶ 21(c). Defendants argue that, to the extent Plaintiff is asserting a claim for negligent failure to test, it should be dismissed because such a claim is not recognized in Pennsylvania. Plaintiff, for her part, does not respond to this argument in her opposing brief.

Pennsylvania courts have explicitly stated that negligent failure to test is not a viable cause of action, and "[they] have found no 'duty to test' that would be the basis of such a claim." *Viguers v. Philip Morris USA, Inc.*, 837 A.2d 534, 541 (Pa. Super. 2003) (citing *Oddi v. Ford Motor Co.*, 234 F.3d 136, 143-44 (3d Cir. 2000) (plaintiff's negligent failure to test claim is nothing more than a routine products liability case)). Consequently, to the extent that Plaintiff's Amended Complaint asserts a claim for negligent failure to test, that claim is dismissed with prejudice.

2. Negligent Sale

Another theory on which Plaintiff bases her claim of negligence is on Defendants' "[f]ailure to . . . sell the Encore knee in a manner so as to render [it] safe for [its] intended purpose." Pl.'s Compl. ¶ 21(a). Although apparently unsure exactly what claim Plaintiff is asserting with this allegation, Defendants nevertheless argue that, to the extent Plaintiff intends to assert a "negligent

marketing claim,” Pennsylvania law does not recognize this claim either. Again, Plaintiff fails to respond to this argument in her opposing brief.

The Court is similarly confused as to what claim Plaintiff is trying to make in this regard. Because of Plaintiff’s failure to defend her claim, the Court will also address the claim in the context of negligent marketing. Defendants are correct in their contention that Pennsylvania courts do not recognize this type of claim. *See Wolfe v. McNeil-PPC, Inc.*, 773 F.Supp.2d 561, 570 (E.D.Pa. 2011); *see also Owens v. Wyeth*, No. 185 EDA 2009, 2010 WL 2965014, at *6 (Pa. Super. Ct. July 26, 2010). Pennsylvania does, however, recognize one narrow exception to this broad prohibition on negligent marketing claims for circumstances in which a drug is promoted in such a way as to negate otherwise-adequate warnings. *See Wolfe*, 773 F.Supp.2d at 570-71; *see also Baldino v. Castagna*, 478 A.2d 807, 810 (1984).

However, Plaintiff pleads absolutely no facts regarding Defendants’ advertising or marketing practices with regard to the artificial knee at issue and therefore does not make any averments that Defendants’ advertising negated the warnings that Defendants provided about the product. In fact, Plaintiff actually alleges that Defendants made no warnings to her about the artificial knee at all, precluding any prospect that this narrow exception to the prohibition on negligent marketing claims would apply. Consequently, insofar as Plaintiff’s Amended

Complaint asserts a claim for negligent marketing, that claim is also dismissed with prejudice.

3. Negligent Failure to Warn

Yet another theory on which Plaintiff bases her claim of negligence is the Defendants' “[f]ailure to provide sufficient warnings as to: (1) the reasonably foreseeable defects in the Encore knee; and (2) the reasonably foreseeable dangers resulting from the implantation and/or usage of the Encore knee.” Pl.’s Compl. ¶ 21(b). Defendants argue first that Plaintiff’s allegations in her Amended Complaint relating to this theory of liability are conclusory and devoid of any factual support, and therefore do not satisfy federal pleading standards under *Twombly* and *Iqbal*. They next contend that Plaintiff’s negligent failure to warn claim is only viable if she pleads the warning that the Defendants should have given and that an alternative warning would have affected her choice to use Defendants’ artificial knee replacement. Finally, Defendants argue that even if Plaintiff did adequately plead her claim under federal pleading standards, her claim is barred by Pennsylvania’s learned intermediary doctrine.

Plaintiff responds that a recent case from the Supreme Court of Pennsylvania, *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), has overruled Pennsylvania’s learned intermediary doctrine and therefore manufacturers of

pharmaceutical drugs and medical devices can face direct liability for their failure to warn the end-consumer of the risks associated with the drug or device.

To plead a claim of negligence, including a claim for negligent failure to warn, a plaintiff must allege that the manufacturer owed a duty to the plaintiff; that the manufacturer breached that duty; and that such breach was the proximate cause of plaintiff's injuries. *See Salvio v. Amgen, Inc.*, 810 F.Supp.2d 745, 752-53 (W.D.Pa. 2011). In her Amended Complaint, Plaintiff alleges that Defendants had a duty to end-user patients, including Plaintiff, "to exercise reasonable care in the design, formulation, manufacture, marketing, promotion, sale, and/or distribution of the Encore knee devices into the stream of commerce so that it would be safely used in a manner and for a purpose for which they were made." Pl.'s Compl. ¶ 20. She next alleges that Defendants breached that duty by failing to warn her of foreseeable defects in the artificial knee and of foreseeable dangers from the knee's implantation. Pl.'s Compl. ¶ 21(b). Finally, she alleges that the defects in the knee were foreseeable to the Defendants and that she suffered injury as a result of their failure to warn her. Pl.'s Compl. ¶ 23. In so pleading, Plaintiff has given the Defendants "fair notice of what the . . . claim is and the grounds on which it rests." *Conley*, 355 U.S. at 47.

Defendants' argument that Plaintiff did not address the warning that was provided and failed to state what warning Defendants should have given is

unavailing. Plaintiff has adequately stated that Defendants gave her no warning at all, and further, that they should have warned her that the tibial post was defective and had a high risk of failure. Moreover, Defendants' argument that Plaintiff must have pled that an alternative warning would have prevented her from utilizing the device is similarly unavailing. Whether or not a different warning would have affected her choice to use the product is not a separate element of a negligence claim that Plaintiff is required to plead in her complaint. Rather, this aspect of the claim goes only to a causation analysis. As mentioned, Plaintiff has adequately pled causation for the purpose of the present motion to dismiss. Accordingly, Plaintiff need not plead that a different warning would have altered her decision-making.

However, Defendants' final argument that the learned intermediary doctrine applies in this case to bar Plaintiff's claim for negligent failure to warn has merit. The learned intermediary doctrine states that "the warnings which are required to be given by the manufacturer [of a prescription drug] must be directed to the physician, not the patient-consumer." *Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 924 (Pa. Super. Ct. 2011) (quoting *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. Ct. 1990)). Though the original cases detailing the doctrine dealt only with manufacturers of prescription drugs, it has since been extended to apply to medical devices as well. See *Mazur v. Merck & Co, Inc.*, 964 F.2d 1348, 1355 (3d Cir.

1992); *see also Lineberger v. Wyeth*, 894 A.2d 141, 150 (Pa. Super. Ct. 2006) (citing *Rosci v. AcroMed, Inc.*, 669 A.3d 959, 968-69 (Pa. Super. Ct. 1995)).

The rationale for the doctrine is that the prescribing physician is more apt to be aware of the patient and his circumstances, including the patient's history, medications, and the amount of the drug that can be safely administered to that patient. *See id.* It is therefore the province of the physician "to use his independent medical judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug." *Id.* As such, the issue in a failure to warn claim is whether the warning given by the manufacturer to the prescribing physician was sufficient; the manufacturer is not required to warn the end-consumer. *See id.*

The Pennsylvania Supreme Court's decision in *Lance v. Wyeth* has cast doubt on whether the learned intermediary doctrine continues to exist as a bar to recovery against a manufacturer. *See generally Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014). In that case, the court stated that "some of the underpinnings of the principle have come into question in light of changed practices in the prescription drug industry. These include the emergence of direct-to-consumer advertising and the evolution of the health-care delivery system encompassing new forms of managed care." *Id.* at 457. However, ultimately the Supreme Court chose not to

consider the “wisdom of modifications or exceptions to the doctrine,” because the case before it did not present the issue for consideration. *Id.*

It is not the province of this Court to extend the law of Pennsylvania and dispose of a doctrine that is still the law of the state. Furthermore, given the rationale behind the rule and the explanation offered by the Pennsylvania Supreme Court as to why “the underpinnings of the principle have come into question,” it is far from evident to this Court that the Pennsylvania Supreme Court would choose to discard the doctrine in its entirety. While the Pennsylvania Supreme Court has signaled its willingness to move away from the doctrine in the context of pharmaceutical drugs, it has demonstrated no such willingness with regards to medical devices, which differ from pharmaceutical drugs in many ways, most notably in that they are not advertised directly to consumers.

As such, Plaintiff can only avoid the application of the learned intermediary doctrine if she were to allege that the warnings given by Defendants to her physician were inadequate, not that the warnings provided directly to her were inadequate. However, nothing in Plaintiff’s Amended Complaint would suggest this idea. In fact, Plaintiff appears to allege only that Defendants did not provide sufficient warnings to her directly. Therefore, insofar as her claim is predicated on a theory of negligent failure to warn, it is dismissed without prejudice with leave to

amend to assert, if possible, that Defendants did not adequately warn Plaintiff's physician about the risks associated with the artificial knee replacement.

4. Negligent Design

The final theory of liability that Plaintiff relies upon for her negligence claim is that of Defendants' "[f]ailure to design . . . the Encore knee in a manner so as to render [it] safe for [its] intended purpose." Pl.'s Compl. ¶ 21(a). Defendants first argue that Plaintiff has not specified the nature of the alleged product defect. They next contend that in order to state a claim for negligent design, Plaintiff must plead that there was an alternative, feasible, safer design available, and must provide factual support that the alternative design existed at the time Defendants made the device for Plaintiff. Plaintiff, for her part, counters that she clearly articulated the design defect present in Defendants' knee replacement as the spontaneous failure of the tibial post and polyethylene. She does not, however, respond to the allegation that she must plead the availability of an alternative, feasible, safer design.

Defendants' first argument, that Plaintiff has not adequately specified the alleged product defect, is unavailing. As already stated, Plaintiff must only plead enough facts to put the Defendant on notice as to what her claim is and on what grounds it rests. *See Conley*, 355 U.S. at 47. Plaintiff has done so here, in alleging that the tibial post and polyethylene of her artificial knee spontaneously failed.

Without discovery, it would be difficult, indeed, for Plaintiff to plead much more than that.

Furthermore, evidence of an alternative, feasible, safer design is not an “absolute prerequisite” to the advancement of a design-defect claim. *Lance*, 85 A.3d at 458 fn. 36. It is an essential element of Plaintiff’s liability case only if her claim is “predicated on a theory of design defect based upon the availability of an alternative safer design.” *Id.* However, it is unclear from Plaintiff’s Amended Complaint what theory of design defect she is alleging. To the extent that she is alleging a theory of design defect based upon the availability of an alternative, safer design, she must plead in her complaint what that alternative, safer design might be. To the extent, then, that as her negligence claim is predicated on negligent design, it is dismissed without prejudice with leave to amend to clarify what theory of design defect she is alleging.

C. Count II Manufacturing Defect

Defendants’ final argument is that Plaintiff has failed to adequately plead a claim under Count II of her Amended Complaint for a manufacturing defect based upon a theory of strict liability. Plaintiff responds that she has in fact presented a sufficient factual basis which demonstrates a plausible claim for relief against Defendants for strict products liability based upon the failure of the defective knee replacement. Further, she argues that she is proceeding on a malfunction theory,

which does not require specific evidence of the defect but rather allows the fact-finder to infer defect based on circumstantial evidence.

Under Pennsylvania law, a plaintiff alleging a manufacturing defect based upon a theory of strict liability must show that: (1) the product at issue was defective; (2) the defect was a proximate cause of the plaintiff's injuries; and (3) the defect causing injury existed at the time the product left the seller's hands. *See Bruesewitz v. Wyeth*, 561 F.3d 233, 255 (3d Cir. 2009) (citations omitted) (citing *Berkebile v. Brantly Helicopter Corp.*, 337 A.2d 893, 898 (1975)).

In this case, Plaintiff has adequately pled all of the elements of a manufacturing defect based upon a theory of strict liability. First, she states that the product at issue, the tibial post and polyethylene, was defective because it spontaneously failed, necessitating a new knee replacement. Pl.'s Compl. ¶ 12-18. Further, she asserts that the failure of the tibial post and polyethylene was the direct cause of her injuries, both physical and financial. Pl.'s Compl. ¶ 31(a)-(f). Finally, Plaintiff alleges that the defect causing injury existed at the time the product left the Defendants' hands. Pl.'s Compl. ¶ 27-28. Consequently, Plaintiff has adequately pled a claim for a manufacturing defect.

Defendants next argue that to the extent Plaintiff intends to proceed on a malfunction theory of liability, she must allege that the device is not available.

Further, they argue, she must present evidence eliminating reasonable secondary causes for the accident.

The malfunction theory of liability allows a plaintiff to use circumstantial evidence, rather than direct evidence, to prove that a product was defective. *See Varner v. MHS, Ltd.*, 2 F.Supp.3d 584 (M.D.Pa. 2014) (Mannion, J.). Under a malfunction theory, the plaintiff must raise inference of a defect through (1) evidence of the occurrence of a malfunction; (2) evidence eliminating abnormal use; and (3) evidence eliminating reasonable, secondary causes for the accident. *See Walters v. General Motors Corp.*, 209 F.Supp.2d 481. 486-87 (W.D.Pa. 2002) (citing *Woodin v. J.C. Penney Co.*, 629 A.2d 974, 975 (Pa. Super. Ct. 1993)). However, the malfunction theory is available only where the product has been destroyed or is otherwise unavailable. *See Barnish v. KWI Bldg. Co.*, 980 A.2d 535, 539 (2009).

The malfunction theory is a theory of liability which can be used to establish the inference of a manufacturing defect. It is not a separate cause of action which must be pled in the complaint. Because Plaintiff adequately pled the three elements of a claim for manufacturing defect, she does not need to plead anything additional relating to her malfunction theory of liability at this stage of the litigation. In fact, it would be nearly impossible for her to prove a negative, that is, the lack of secondary causes, without first being confronted with what these other

potential secondary causes might be. As such, Defendants' Motion to Dismiss with regard to Count II of Plaintiff's Amended Complaint is denied. However, to the extent that Plaintiff intends to proceed on a malfunction theory at a later stage in the proceeding, she must prove that the defective product was unavailable.

III. CONCLUSION

Defendants' Motion to Dismiss is granted in part and denied in part. Insofar as Plaintiff's Amended Complaint asserts a claim for negligent failure to test and negligent sale in Count I, those claims are dismissed with prejudice. Insofar as Plaintiff's Amended Complaint asserts a claim for negligent failure to warn and negligent design in Count I, those claims are dismissed without prejudice with leave to file a second amended complaint in accordance with this Court's decision. Defendants' Motion to Dismiss is denied with regard to Plaintiff's claim in Count II for manufacturing defect based upon a theory of strict liability.

BY THE COURT:

/s Matthew W. Brann
Matthew W. Brann
United States District Judge